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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,858	05/29/2001	Yves Bayon	P07231US00/L	4715

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/856,858

Applicant(s)

BAYON ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
        1. ☐ Certified copies of the priority documents have been received.  
        2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment of claims 3-7, 9, 10, 12, 13, 15-17, 19-22, 25 and 26 in Paper No. 2, filed 29 May 2001, is acknowledged. Claims 1-26 are pending.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See same issue in claims 2, 5, 6, 9, 20, and 22.

The term "functionalized" in claim 12 renders the claim indefinite as it is unclear what functions would be carried out at the amino acid level, for example.

Regarding claim 17, the phrase "especially" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "highly" in claim 21 is a relative term which renders the claim indefinite. The term "highly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Claim 24 is indefinite as it is unclear how the “collogenic component” differs from the “crosslinked collagen fibers.” The terms are used to distinguish two different layers, however, the distinguishing elements of the two layer are not made clear in the language of the claim.

There is lack of antecedent basis for “wet state” in claim 25, which renders the claim indefinite. Additionally, the use of the phrase “network of collagen fibers” is indefinite as the terms “network” and “fibers” are used in the parent claim 24 to describe two distinct elements. It is not clear if the “network of collagen fibers” is referring to the “crosslinked networks” of the entire biocomposite, or the “crosslinked collagen fibers” of one of the layers of the entire biocomposite that is recited in parent claim 24.

Claims 2-23 and 25-26 are indefinite as they depend from the above claims and do not clarify the ambiguity.

### ***Claim Objections***

3. Claims 1-23 are objected to because the steps of the process are not clearly separated. Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP 608.01(i)-(p).

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 3-23 are rejected under the judicially created doctrine of double patenting over claims 19-39 of U.S. Patent No. 6,391,939 B2 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: U.S. Patent No. 6,391,939 B2 recites a process of making a biocompatible, biodegradable collagenic material that comprises the step of crosslinking the collagenic material with beta irradiation at a dose of 25 kilogreys (see claims 19, 32-34; regarding claims 1, 2, 19-22). The collagen component was brought to a neutral pH prior to irradiation (see claim 22; regarding claim 5). The collagen component is made from an aqueous solution of 2-6% collagen

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that is used to form of gel or in solution (see claims 21 and 37, column 7, lines 15-20; regarding claims 3, 4, 6). Claim 35 teaches the reduced helical structure (regarding claim 7 and 8). Claims 23 and 24 teach the heating of the collagen component to temperatures between 37 and 50 C (regarding claim 9). Claims 20-21 teaches the oxidation of collagen using periodic acid (regarding claims 10 and 11). Claim 39 teaches the digestion of the collagenic material the functional elements with pepsin (regarding claim 12). Claims 19 and 25-26 teaches at least one hydrophobic macromolecular additive comprising PEG having a MW over 3000 Daltons (regarding claims 13-16). Claim 28 teaches starch, dextran and cellulose as an additive (regarding claim 17 and 18). Claim 36 teaches that the collagenic material is applied to a support using the procedure of claims 19 and 35 (regarding claim 23).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

6. Claims 1-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-39 of U.S. Patent No. 6,391,939 B2 in view of Okamura *et al.* (US Patent 3,808,113). Although the conflicting claims are not identical, they are not patentably distinct from each other because the process of making a biocompatible, biodegradable collagenic material comprises the step of crosslinking the collagenic material with beta irradiation at a dose of 25 kilogreys (see claims 19, 32-34; regarding claims 1, 2, 19-22).

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The collagen component was brought to a neutral pH prior to irradiation (see claim 22; regarding claim 5). The collagen component is made from an aqueous solution of 2-6% collagen that is used to form of gel or in solution (see claims 21 and 37, column 7, lines 15-20; regarding claims 3, 4, 6). Claim 35 teach the reduced helical structure (regarding claim 7 and 8). Claims 23 and 24 teach the heating of the collagen component to temperatures between 37 and 50 C (regarding claim 9). Claims 20-21 teaches the oxidation of collagen using periodic acid (regarding claims 10 and 11). Claim 39 teaches the digestion of the collagenic material the functional elements with pepsin (regarding claim 12). Claims 19 and 25-26 teaches at least one hydrophobic macromolecular additive comprising PEG having a MW over 3000 Daltons (regarding claims 13-16). Claim 28 teaches starch, dextran and cellulose as an additive (regarding claim 17 and 18). Claim 36 teaches that the collagenic material is applied to a support using the procedure of claims 19 and 35 (regarding claim 23).

Okamura *et al.* teach the method of crosslinking the collagenic material with beta irradiation and teach that the moisture content must be above 20% (see at least column 3, lines 20-25; regarding claims 2 and 22). Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made that the moisture content would need to be above 20% for beta irradiation.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Carr *et al.* (US Patent 5,733,337). Carr *et al.* teach a biocomposite, or prosthesis made from collogenic material, that is biocompatible, nontoxic, sterile and has a controlled rate of biodegradation that is able to be applied by sutures (see abstract, claim 1, and column 5, line 16). The prosthetic taught by Carr *et al.* consist of essentially two layers. The first layer is made from collagenous tissue sources, termed ICL by Carr *et al.*, which are layered the a desired thickness and crosslinked together to form a collogenic film (see columns 2-4, and claim 1). To this film an additional collagenous layer is added and bonded to the collagen layer to form a smooth flow surface. This second layer is made from gels or a fibril collagen dispersion, in which the collagen would have partially lost its helical structure (see column 6, lines 22-45; regarding claim 24). Once the two layers are combined, the prosthetic is irradiated (see column 6, line 53-55). Thus, the reference anticipates the claimed invention.



9. Claims 1 and 3-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Tayot *et al.* (US Patent 6,391,939). Tayot *et al.* teach the process of making a biocompatible, biodegradable collagenic material comprises the step of crosslinking the collagenic material with beta irradiation at a dose of 25 kilogreys (see claims 19, 32-34; regarding claims 1, 19-22). The collagen component was brought to a neutral pH prior to irradiation (see claim 22; regarding claim 5). The collagen component is made from an aqueous solution of 2-6% collagen that is used to form of gel or in solution (see claims 21 and 37, column 7, lines 15-20; regarding claims 3, 4, 6). Claim 35 teach the reduced helical structure (regarding claim 7 and 8). Claims 23 and 24 teach the heating of the collagen component to temperatures between 37 and 50 C (regarding claim 9). Claims 20-21 teaches the oxidation of collagen using periodic acid (regarding claims 10 and 11). Claim 39 teaches the digestion of the collagenic material the functional elements with pepsin (regarding claim 12). Claims 19 and 25-26 teaches at least one hydrophobic macromolecular additive comprising PEG having a MW over 3000 Daltons (regarding claims 13-16). Claim 28 teaches starch, dextran and cellulose as an additive (regarding claim 17 and 18). Claim 36 teaches that the collagenic material is applied to a support using the procedure of claims 19 and 35 (regarding claim 23). Thus, the reference anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tayot *et al.* (US Patent 6,391,939) in view of Okamura *et al.* (US Patent 3,808,113). Tayot *et al.* teach the process of making a biocompatible, biodegradable collagenic material comprises the step of crosslinking the collagenic material with beta irradiation at a dose of 25 kilogreys (see claims 19, 32-34; regarding claims 1, 2). Tayot *et al.* does not teach that the moisture content be greater than 30%.

Okamura *et al.* teach the method of crosslinking the collagenic material with beta irradiation and teach that the moisture content must be above 20% (see at least column 3, lines 20-25; regarding claims 2 and 22).

Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made that the moisture content would need to be above 20% for beta irradiation. A person of ordinary skill in the art would have been motivated and expected success by using a moisture content of greater than 20% (or 30-40% are recited in the claim), as Okamura *et al.* teach that moisture content is a vital factor for success. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

### ***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843.

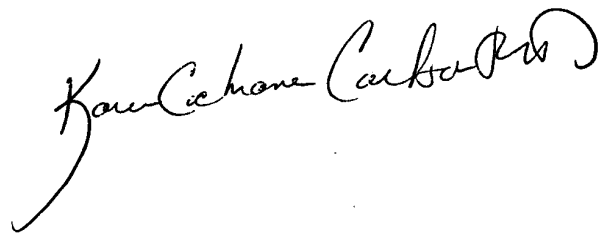
The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
May 5, 2003

SKS

A handwritten signature in cursive script, reading "Karen Cochrane Carlson, Ph.D.", written in black ink.

KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER